

REMARKS

I. INTRODUCTION

Claims 1, 14 and 20 have been amended. Claim 6, 9 and 16 have been amended. Thus, claims 1-5, 7, 8, 10-15 and 17-26 are now pending in the present application. No new matter has been added. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

II. THE 35 U.S.C. § 112 REJECTION SHOULD BE WITHDRAWN

Claims 1 - 5, 7, 8, 10 - 15 and 17 - 26 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. *5/19/08 Office Action*, p. 4. The Examiner states that a negative limitation must be explicitly set forth in the Specification and that the limitation of a “non-annular electrode” is not supported in the disclosure of the invention. *Id.* at p. 5.

It is respectfully submitted that a negative limitation is considered definitive so long as the boundaries of patent protection sought are set forth definitely and the limitation has basis in the original disclosure. *See* MPEP 2173.05(i). The specification describes the electrodes 112, 113 as “C-shaped with an opening 131 of approximately 110 degrees.” *Specification*, p. 3, ¶ [0029]. Additionally, the electrodes 112, 113 and 122, 123 are shown to extend around only a portion of a circumference of the probe 100. *See* Figs. 3b, 3c. It is also noted that the electrodes are not described as being annular or ring-like anywhere in the specification. Therefore, all of the electrodes described and shown in the original disclosure will be understood by those of skill in the art to be non-annular.

Thus, it is respectfully submitted that the limitation of a “non-annular electrode,” as recited in independent claims 1, 14 and 20, clearly has basis in the original disclosure and that the rejection of this claim should be withdrawn. Because claims 2- 5, 7, 8 and 10 - 13, 15 and 17 - 19, and 21- 26 depend from and include all of the limitations of claims 1, 14 and 20, respectively,

it is respectfully submitted that these claims are also in condition for allowance and that the rejection of this claim should be withdrawn.

III. THE 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a) REJECTION SHOULD BE WITHDRAWN

Claims 1-5, 7, 8, 10, 12-15 and 17-26 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Published Appln. No. 2003/0097167 to Friedman ("Friedman") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Friedman in view of U.S. Patent No. 6,855,116 to Atlee III ("Atlee"), or in view of U.S. Patent No. 6,266,549 to Melnikoff et al. ("Melnikoff") or in view of U.S. Published Appln. No. 7,212,867 to Van Venrooij et al. ("Venrooij"). 5/19/08 Office Action, p. 2.

Claim 1 recites a medical apparatus comprising "a flexible probe for accessing a patient's esophagus via the mouth, the probe, when in an operative position, extending from a proximal end which remains outside the patient to a distal end within the esophagus" in combination with "an echocardiography transducer coupled to the distal end of the probe so that, when the probe is in the operative position, the echocardiography transducer is at a predetermined location within the esophagus relative to the heart to perform a transesophageal echocardiography procedure" and "a flexible sheath sized to be received one of permanently and removably over the probe, the sheath including *a non-annular electrode that is embedded in the sheath* so that the electrode, when in an operative position, contacts the esophagus to deliver a cardioversion current to the heart." Support for the amended claim language may be found at p. 4, ¶ [0041] of the Specification.

In contrast, Friedman discloses an esophageal probe with annular electrode rings that are clamped over a silicone sheet assembly wrapped around a distal end of the probe. Friedman describes the distal portion 14 of an elongated flexible member 10 as being wrapped with a silicone sheet subassembly 30 that contains electrical contacts 25 and conductors 24 to each contact 25. *Friedman*, p. 3, ¶ [0032]. Clamped over the electrical contacts 25 of the silicone

sheet subassembly 30 are electrode rings 26. *Id.* at ¶ [0031] and [0032]. As the electrode rings 26 are clamped over the silicone sheet subassembly 30, it is respectfully submitted that the electrode rings 26 are not embedded within the silicone sheet subassembly 30. Additionally, the electrical contacts 25 are merely a contact point between the conductors 24 and the electrode rings 26. *Id.* at ¶ [0032]. The electrical contacts 25 cannot and do not act as electrodes as they are always covered by the electrode rings 26 and act only to expose an end of the conductor 24 such that it may contact the electrode rings 26. *Id.* at ¶ [0033]; *see* Fig. 2D. Thus, it is respectfully submitted that Friedman does not disclose a “*sheath embedded with a non-annular electrode*,” as recited in claim 1.

In the alternative, the Examiner asserts that it would have been obvious to one of ordinary skill in the art to combine the device of Friedman with the device of Atlee, Melnikoff or Van Venrooij. 5/19/08 *Office Action*, p. 7.

It is respectfully submitted that Atlee does not cure the deficiency of Friedman, as discussed above. Atlee discloses various types of electrodes that are mounted onto an outer wall of a carrier member. Specifically, Atlee teaches bipolar electrodes 48, 50 mounted onto carrier member 22; a pair of ring-type electrodes 90 engaged with an outer wall of a carrier member 88; a patch-type electrode array 98 mounted on an outer surface of a carrier member 96;. *Atlee*, col. 6, ll. 2-6; col. 8, ll. 9-12 and 30-35; *see* Fig. 10. Thus, as each of the electrodes are *mounted* on the carrier member, Atlee does not show or suggest electrodes that are embedded within a sheath. Therefore, it is respectfully submitted that neither Friedman nor Atlee, either alone or in combination show or suggest a “*sheath embedded with a non-annular electrode*,” as recited in claim 1.

It is also respectfully submitted that Melnikoff does not cure the deficiency of Friedman, as discussed above in regard to claim 1. Melnikoff discloses an electrode 17 comprising an electrode dome 50 arranged on a unitary base 52, which are integrally formed. *Melnikoff*, col. 6, ll. 11-16. The electrode 17 is attached to a tube-like probe via connectors 55a and 55b. *Id.* at

col. 7, ll. 40-42; *see* Fig. 2. Thus, it is respectfully submitted that neither Friedman nor Melnikoff, either alone or in combination, show or suggest a “*sheath embedded with a non-annular electrode*,” as recited in claim 1.

It is respectfully submitted that Van Venrooij does not cure the deficiency of Friedman, as discussed above in regard to claim 1. Van Venrooij discloses a directional brain stimulation lead assembly for implantation in the brain. It is respectfully submitted that it would not have been obvious to one of ordinary skill in the art to modify the device of Friedman, an esophageal probe, with the electrodes of Van Venrooij since they serve drastically different purposes. Moreover, the lead assembly of Van Venrooij provides a windowed insulating member 10 that has a substantially tubular body 12 with a window 16 such that when the insulating member 10 is placed over a lead body 20, portions of electrodes 24 are exposed. *Van Venrooij*, col. 6, ll. 34-40. Each electrodes 24 extends *about an exterior wall* of the lead body 20 and is thus not embedded within the insulating member 10. *Van Venrooij* at col. 6, ll. 1-5. Thus, it is respectfully submitted that neither Friedman nor Van Venrooij, either alone or in combination, show or suggest a “*sheath embedded with a non-annular electrode*,” as recited in claim 1.

Accordingly, it is respectfully submitted that claim 1 is not rendered obvious by Friedman alone or by Friedman in view of Atlee, Melnikoff or Van Venrooij and that the §102(e) and § 103(a) rejections of this claim should be withdrawn. Because claims 2-5, 7, 8, 10, 12-13 and 24-26 depend from and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Similarly, claim 14 recites a cardioversion mechanism comprising “a flexible sheath sized to be received one of permanently and removably over a transesophageal echocardiography probe, *the flexible sheath including a non-annular electrode assembly that is embedded in the sheath*, wherein, when the sheath is received by the echocardiography probe, electrodes of the electrode assembly are located at a predetermined location with respect to the echocardiography probe.”

For at least the same reason as discussed above in regard to claim 1, it is respectfully submitted that claim 14 is neither anticipated by Friedman nor rendered obvious by Friedman in view of Atlee, Melnikoff or Venrooij and that the rejections to this claim should be withdrawn. Because claims 15 and 17-19 depend from and, therefore, include the limitations of claim 14, it is respectfully submitted that these claims are also allowable.

Claim 20 recites a method comprising a "inserting into the patient's esophagus a device comprising a flexible probe having an echocardiography transducer coupled to a distal end thereof and a flexible sheath sized to be received one of permanently and removably over the probe, *the sheath including at least one non-annular cardioversion electrode that is embedded in the sheath*" in combination with "performing an echocardiography to analyze a condition of the heart" and "applying electric current to the at least one electrode to supply a cardioversion current to the heart by contacting the electrode to the esophagus when the echocardiography does not contraindicate cardioversion.

For at least the same reason as discussed above in regard to claims 1 and claim 14, it is respectfully submitted that claim 20 is neither anticipated by Friedman nor rendered obvious by Friedman in view of Atlee, Melnikoff or Venrooij and that the rejections to this claim should be withdrawn. Because claims 21-23 depend from and, therefore, include the limitations of claim 20, it is respectfully submitted that these claims are also allowable.

Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Friedman or, in the alternative, as unpatentable over Friedman in view of Shaddock. 5/19/08 *Office Action*, p. 10. As discussed above, Friedman does not disclose or suggest "a sheath including a non-annular electrode," as recited in claim 1, from which claim 11 depends. Accordingly, it is respectfully submitted that claim 11 is allowable as being dependent on an allowable base claim and that the Examiner should withdraw the 35 U.S.C. § 103(a) rejection of claim 11.

CONCLUSION

In light of the foregoing, Applicant respectfully submits that all of the presently pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

Dated:

Aug 19, 2008

By:

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